

**PATENT COOPERATION TREATY****PCT****INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 10123-00702	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/US2005/000760	International filing date ( <i>day/month/year</i> ) 14 January 2005 (14.01.2005)	Priority date ( <i>day/month/year</i> ) 29 January 2004 (29.01.2004)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant BOSTON SCIENTIFIC SCIMED, INC.			

<p>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>																								
<p>3. This report contains indications relating to the following items:</p> <table> <tbody> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </tbody> </table> <p>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).</p>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input checked="" type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Authorized officer <b>Dorothée Mülhausen</b> e-mail: pt01@wipo.int</p>	

# PATENT COOPERATION TREATY

REC'D 21 JUL 2005

WIPO

PCT

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

### FOR FURTHER ACTION

See paragraph 2 below

International application No.  
PCT/US2005/000760

International filing date (day/month/year)  
14.01.2005

Priority date (day/month/year)  
29.01.2004

International Patent Classification (IPC) or both national classification and IPC  
A61M39/22, A61M39/24, A61M25/00

Applicant  
BOSTON SCIENTIFIC SCIMED, INC.

#### 1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

#### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

#### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/000760

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - a sequence listing
    - table(s) related to the sequence listing
  - b. format of material:
    - in written format
    - in computer readable form
  - c. time of filing/furnishing:
    - contained in the international application as filed.
    - filed together with the international application in computer readable form.
    - furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/000760

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application,
- claims Nos. 18-21

because:

- the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- no international search report has been established for the whole application or for said claims Nos. 18-21
- the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form                    has not been furnished

does not comply with the standard

the computer readable form      has not been furnished

does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See separate sheet for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

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**Box No. IV Lack of unity of invention**

1.  In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
  - paid additional fees.
  - paid additional fees under protest.
  - not paid additional fees.
2.  This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
  - complied with
  - not complied with for the following reasons:

**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
  - all parts.
  - the parts relating to claims Nos. 1-17

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or  
industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	1-9,11-13,15-17
	No:	Claims	10,14
Inventive step (IS)	Yes:	Claims	7,9
	No:	Claims	1-6,8,10-17
Industrial applicability (IA)	Yes:	Claims	1-17
	No:	Claims	

**2. Citations and explanations**

**see separate sheet**

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

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International application No.  
PCT/US2005/000760

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**1 Concerning Item IV**

In the light of WO-A-97/23255 (D1), being considered as the closest prior art, claims 1, 10 and 14 have a common special technical feature, namely that the valve has a nonthrombogenic coating (see Item V). Since other technical features of claims 1, 10 and 14 are known from D1 and claim 18 does not include a technical feature corresponding to the special technical feature of the other independent claims, claim 18 is not so linked as to form a single general inventive concept with the remaining independent claims. Hence, said claims lack unity and are considered to relate to two possible groups of inventions as indicated below. The separate inventions/groups of inventions are:

Claims 1-17: Pressure activated valve having a nonthrombogenic coating on fluid contacting surfaces or a catheter having such a valve

Claims 18-21: Pressure activated valve having a plurality of flexible members stacked on one another

**2 Concerning Item V.**

- 2.1 D1 discloses a catheter comprising a lumen (9) and a valve (5) having a flexible membrane (17) including a slit (7).
- 2.2 In the light of D1, the subject-matter of claim 1 is considered to differ from the disclosure of D1 by that the valve has a nonthrombogenic coating. WO-A-97/26931 (D2) discloses a medical device having a valve structure including an antithrombogenic agent for preventing the clotting of blood. Consequently, in the light of the teaching of D2, it would be obvious for the skilled person to arrive at the subject-matter of claims 1 and 6, should he face the problem of preventing clotting of blood at the valve of D1. Thus, the subject-matter of claim 1 does not meet the requirement of Article 33(3) PCT.
- 2.3 In addition, the technical features of dependent claims 2-4 and 8 appear to be disclosed by D1 and the technical feature of claim 5 appears to be obvious from the disclosure of US-A-6 152 909 (D3). Thus, claims 2-5 and 8 do not meet the requirement of Article 33(3) PCT.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

International application No.

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- 2.4 D2 discloses a tubular device being suitable for dialysis, comprising an elongated body (32, 46), a lumen and a valve (48) having a nonthrombogenic coating as defined in claims 10 and 14. Consequently, the subject-matters of claims 10 and 14 do not meet the requirement of Article 33(2) PCT.
- 2.5 The technical features of the dependent claims 11-13 and 15-17 appear to be obvious from the combined teaching of D1 and D2 or US-A-4 447 237 (D5). Thus, said claims do not meet the requirement of Article 33(3) PCT.
- 2.6 The technical features of claims 7 and 9 do not appear to be derivable from any of the cited documents in an obvious manner. Thus, the subject-matters of said claims appear to meet the requirements of Article 33(2) and (3) PCT.
- 2.7 The industrial applicability (Article 33(4) PCT) of a device according to the claims 1-17 is self-evident.

**3 Concerning Item VII**

The closest prior art (D1) has not been identified as required by Rule 5(a)(ii) PCT. Furthermore, the independent claims are not in the two-part form as required by Rule 6.3(b) PCT. In addition, the claims do not include reference signs in parentheses as required by Rule 6.2(b) PCT.